

**REMARKS**

The Office Action dated August 25, 2004 presents the examination of claims 1, 5-9, 16-18, 21-23, and 31-35. Claims 1, 5-9, and 17 are canceled herein. Claims 16, 18, 21, 22, and 31 are amended. Support for the subject matter added to claim 16 is found in the specification, particularly on page 17, lines 7-14, and in Examples 3-5 and 8-12. Claims 18 and 31 are amended to update claim dependency, while claims 21 and 22 are amended to clarify claim language. No new matter is inserted into the application. Upon entry of this Reply, claims 16, 18, 21-23, and 31-35 will be pending.

**Claim Interpretation (Paragraph 3, page 3 of the Office Action)**

The Examiner discusses the interpretation of "DNA synthesis reaction-enhancer" as recited in claim 1. As noted above, claim 1 is canceled. Claim 16, as amended, is directed to a DNA synthesis reaction composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase. The DNA synthesis reaction-enhancer is selected from the group consisting of a transition metal complex and water-soluble acidic macromolecular substances or water-soluble salts thereof. The water-soluble acidic macromolecular substances are

further defined as one or more of the following: sulfated-fucose-containing polysaccharides, dextran sulfate, carrageenan, heparin, rhamnam sulfate, dermatan sulfate (chondroitin sulfate B), heparan sulfate, hyaluronic acid, alginic acid, pectin, polyglutamic acids, polyacrylic acids, polyvinyl sulfates, polystyrene sulfates, and DNAs which do not serve as templates for subject DNA synthesis or as primers.

**Maintained Rejections under 35 U.S.C. § 102 (Pages 7-8 of the Office Action)**

**Blakely '162 (Paragraph 5, page 4 of the Office Action)**

The Examiner maintains the rejection of claims 1, 16, and 17 under 35 U.S.C. § 102(b) for allegedly being anticipated by Blakely '162 (U.S. Patent 5,418,162). Claims 1 and 17 are canceled, thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of claim 16. Reconsideration and withdrawal of the instant rejection are respectfully requested.

Claim 16, as amended, is directed to a DNA synthesis reaction composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase. Blakely '162 merely teaches heparin sulfate and its use to prevent non-specific adsorption of nucleic acid probes to

filters. Blakely '162 fails to disclose a composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase, wherein the DNA synthesis reaction-enhancer is, for example, heparin sulfate.

For this reason, Blakely '162 fails to anticipate the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Koster '906 and Sorge '772 (Paragraphs 6-7, pages 5-7 of the Office Action)

The Examiner maintains the rejection of claims 1, 16-18, 21-23, and 31-35 under 35 U.S.C. § 102(e) over Koster '906 (U.S. Patent 5,928,906), and the rejection of claims 1, 16-18, 21-23, and 31-35 under 35 U.S.C. § 102(e) over Sorge '772 (U.S. Patent 5,556,772). Claims 1 and 17 are canceled, thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

Koster '906 and Sorge '772 disclose nucleic acid amplification carried out in the presence of  $Mg^{2+}$  and two polymerases. The Examiner asserts that the term "cationic complex" (as formally used in claim 1) encompasses  $Mg^{2+}$ . Further, the Examiner considers that

DNA primers, as disclosed by Koster '906 and Sorge '772, are encompassed by the phrase "DNAs which do not serve as templates for subject DNA synthesis."

Claim 16, as amended, is directed to a DNA synthesis reaction composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase. The DNA synthesis reaction-enhancer is defined as, for example, a transition metal complex or DNAs which do not serve as templates for subject DNA synthesis or as primers. Claim 16 does not recite "cationic complex."

Koster '906 and Sorge '772 fail to disclose a composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase, wherein the DNA synthesis reaction-enhancer is, for example, a transition metal complex or DNAs which do not serve as templates for subject DNA synthesis or as primers.

For these reasons, Koster '906 and Sorge '772 fail to anticipate the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Barton '556 (Paragraph 8, pages 7-8 of the Office Action)

The Examiner maintains the rejection of claims 1, 6-8 and 16

under 35 U.S.C. § 102(b) for allegedly being anticipated by Barton '556 (U.S. Patent 5,225,556). Claims 1 and 6-8 are canceled, thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of claim 16. Reconsideration and withdrawal of the instant rejection are respectfully requested.

Claim 16, as amended, is directed to a DNA synthesis reaction composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase. Barton '556 merely teaches cobalt(III) complex and rhodium(III) complex having a phenanthroline backbone. Barton '556 fails to disclose a composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase, wherein the DNA synthesis reaction-enhancer is, for example, a transition metal complex. Claim 16, unlike former claim 1, does not recite "cationic complex."

For this reason, Barton '556 fails to anticipate the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

**Rejection under 35 U.S.C. § 112, first paragraph (Paragraphs 9-10, pages 8-9 of the Office Action)**

The Examiner rejects claims 1, 5-9, 16-18, 21, and 31-35 under 35 U.S.C. § 112, first paragraph for allegedly containing new matter. Claims 1, 5-9, and 17 are canceled, thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that there is no support for "water-soluble" acidic macromolecular substances in the specification. Instead, the Examiner asserts that the specification only supports "water-soluble salts" of the acidic macromolecular substances. Claim 16 is amended to clearly define the "salts" as "salts of water-soluble acidic macromolecular substances."

Withdrawal of the instant rejection is therefore respectfully requested.

**Rejection under 35 U.S.C. § 112, second paragraph (Paragraphs 11-12, pages 9-10 of the Office Action)**

The Examiner rejects claims 1, 5-9, 16-18, 21-22, and 31-35 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Claims 1, 5-9, and 17 are canceled, thus rendering

rejection thereof moot. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

A) The Examiner asserts that it is not clear to which compounds the recitation of "salts thereof" applies. As noted above, claim 16 is amended to recite that the salts encompassed by claim 16 is salts of water-soluble acidic macromolecular substances.

The Examiner also asserts that the recitation of "subject DNA synthesis" is not clear. Applicants respectfully disagree with the Examiner on this point. Claim 16, as amended, recites "DNAs which do not serve as templates for subject DNA synthesis or as primers." Applicants respectfully submit that the skilled artisan would understand that the DNAs described in this phrase are those which are not amplified, for example, during PCR and those which do not serve as primers for DNA amplification.

B) The Examiner points out that the recitation of "the other polymerase" in claim 21 lacks antecedent basis in claim 18. In order to overcome this rejection, the phrase "the other" is amended to "one."

C) The Examiner states that the recitation of "not reduced" in claim 22 is unclear. Applicants amend claim 22 to recite that the

activity of the polymerase is not reduced in comparison to the wild-type.

Applicants respectfully submit that the pending claims particularly point out and distinctly claim the subject matter which is the present invention such that the requirements of 35 U.S.C. § 112, second paragraph are met. Withdrawal of the instant rejection is therefore respectfully requested.

**Rejection under 35 U.S.C. § 102 (Paragraphs 13-15, pages 10-11 of the Office Action)**

The Examiner makes the following new rejections under 35 U.S.C. § 102:

- 1) Claims 1 and 16 over the Sigma Catalog (1996);
- 2) Claims 1, 5, and 16 over Sakai '652 (U.S. Patent 6,207,652); and
- 3) Claims 1, 6-9, and 16 over Tavitigian '206 (U.S. Patent 5,789,206).

Claims 1 and 5-9 are canceled, thus rendering the rejection thereof moot. Applicants respectfully traverse the rejection of claim 16. Reconsideration and withdrawal of the instant rejection are respectfully requested.

Claim 16, as amended, is directed to a DNA synthesis reaction



composition comprising a DNA synthesis reaction-enhancer, a DNA polymerase, and components necessary for DNA synthesis using DNA polymerase. None of the prior art references cited by the Examiner disclose a DNA synthesis reaction composition as defined in claim 16. In particular, the Sigma catalog teaches compounds such as dextran sulfate, heparin, etc., but fails to teach a DNA synthesis reaction composition. Sakai et al. teaches sulfated-fucose-containing polysaccharides, but fails to teach a DNA synthesis reaction composition. Tavtigian '206 teaches a cationic complex, but fails to teach a DNA synthesis reaction composition.

For these reasons, the cited references fail to anticipate the present invention as defined in the claims. Withdrawal of the instant rejection is therefore respectfully requested.

### **Conclusion**

Applicants respectfully submit that the above remarks and/or amendments to the instant claims fully address and properly overcome, render moot, or otherwise accommodate all of the pending rejections/objections of record. All of the present claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

Pursuant to 37 C.F.R. 1.17 and 1.36(a), the Applicants respectfully petition for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of \$450.00 is attached.

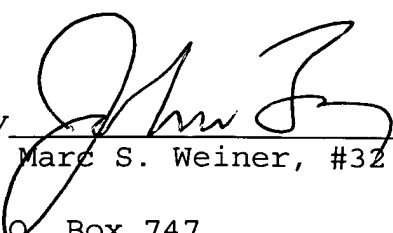
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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